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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/052,855	03/31/98	BILLING-MEDEL	P 6064.US.P1

EXAMINER

HM22/0830

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JOHNSON, N	PAPER NUMBER
ART UNIT	18

1642

DATE MAILED:

08/30/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 6/14/99

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

Shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, never is longer, from the mailing date of this communication. Failure to respond within the period for response will cause application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-39 is/are pending in the application.
Of the above, claim(s) 1-9, 17-24, 26-29, 31-34, 36-37 is/are withdrawn from consideration.
Claim(s) _____ is/are allowed.
Claim(s) 10-16, 25, 30, 35, 38-39 is/are rejected.
Claim(s) _____ is/are objected to.
Claim(s) _____ are subject to restriction or election requirement.

Specification Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

Certified copies not received: _____

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Comments(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGES..

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1. Claims 1-39 are pending.

Claims 1-9, 17-24, 26-29, 31-34, 36-37 remain withdrawn from examination.

Claims 10-11, 14-15, 25, 30, 38-39 have been amended.

Claims 10-16, 25, 30, 35 and 38-39 are examined on the merits.

2. This application contains non-elected claims 17-24, 26-29, 31-34, 36-37. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. The rejection of claims 38 and 39 under 35 U.S.C. § 101 is withdrawn.

4. The rejection of claims 10-16, 25, 30, 35 and 38-39 under 35 U.S.C. 112, second paragraph, is maintained.

~~with~~ The recitation "hybridizing to" in claim 11 and amended claims 10, 15, 30 remains vague and indefinite. The applicant argues that the "term selectively 'hybridizing to' has an art recognized meaning" and that "examples of selective hybridization are described throughout the specification." This is not found persuasive. While the methodologies of DNA hybridization are indeed art known, it is also art known that the specific stringency conditions used determine the breadth of which polynucleotide sequences will hybridize to the designated polynucleotide sequence and which ones will not. Thus, stringency conditions determine the breadth of the

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claim. Absent the recitation of specific hybridization conditions in the claim, the metes and bounds of the claimed polynucleotides are unclear

with The recitation “% identity” in claims 10, 11, 15, 25, 38, 39 and amended 30 remains vague and indefinite. The applicant argues that the specification “discusses the use of available programs for calculating % identity or similarity between sequences. Applicant submit that the use of default parameters is routine and well within the abilities of one having skill in the art.” This is not found persuasive. Page 12 of the specification merely provides an open ended listing of many of the different programs available for calculating identity between sequences. This is inadequate. Each of these different programs will give varying results. Further, while the use of default parameters is well within the abilities of one having skill in the art, nothing in the specification or the claims indicates the scope of the claims are to be restricted to only default parameters.

with The recitation “at least one epitope” in claims 14, 25, 30 remains vague and indefinite. The applicant argues that the specification provides a definition of an “epitope” (p.17, line 30- p.18, line 17). This is not found persuasive. All of the definitions appear to be based on “spatial confirmations.” The instant invention has been characterized only to the extent of linear confirmation (polynucleotide sequences). Thus, the nature of an “epitope” remains unclear.

The rejections based on the recitations “is produced by recombinant techniques” (claim 12) and “is produced by synthetic techniques” (claim 13) are withdrawn.

The rejection based on the “having” in claim 10 is withdrawn.

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The rejections based on the recitations “CS141 polynucleotide” (claim 10), “CS141 gene” (claim 11), “CS141 epitope” (claims 14,25, 30), “CS141” (claim 15) and “CS141 protein” (claim 38) is withdrawn.

The rejection based on the recitation “derived from” in claims 11 and 15 is withdrawn.

The rejection based on the recitation “and fragments and complements thereof” in claim 30 is withdrawn.

5. The rejection of claims 11-16 and 38-39 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn.

6. The rejection of claims 14, 25 and 30 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claims is maintained. The rejection of claims 10-13, 15-16, 35 and 38-39 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claims is withdrawn.

Amended claims 14, 25, 30 are broadly drawn to “at least one epitope.” Given the uncertainty of what constitutes an epitope (discussed in paragraph 4, above, one of skill in the art can not predictably make and use the claimed epitope.

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Rejections based on claims drawn to a "CS141 polynucleotide" (claim 10), "CS141 gene," (11-14) "an open reading frame derived from CS141" (claim 15), "CS141" (claims 14, 20, 25) and "CS141 protein" (claim 38) are withdrawn.

Rejections based on claims broadly drawn to a "gene" (claims 11, 38 and 3) are withdrawn.

7. The rejection of claims 11-13 under 35 U.S.C. 102(b) as being anticipated by p.167 of the 1994-1995 Promega catalog is withdrawn.

8. The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over p.167 of the 1994-1995 Promega catalog is withdrawn.

9. The rejection of claims 11-16, 25, 30 and 39 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,733,748 (filed June 6, 1995) is withdrawn.

10. The rejection of claims 10 and 35 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,733,748 (filed June 6, 1995) is withdrawn.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Nancy A. Johnson', with a long, sweeping horizontal line extending to the right.

Nancy A Johnson
Primary Examiner

August 27, 1999